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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/708,724

03/19/2004

David R. Duncan

38-21(52503)B

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04/05/2006

MONSANTO COMPANY

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ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)

ST. LOUIS, MO 63167

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/708,724

Applicant(s)

DUNCAN ET AL.

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/18/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-8, 16 and 17) in the reply filed on February 13, 2006 is acknowledged. The traversal is on the ground(s) that all Applicant believes that it would not create an undue burden on the Examiner to conduct a search encompassing all of the claims (see page 2nd paragraph of 'Response to Election/Restriction Requirement' filed February 13, 2006). This is not found persuasive because the inventions are distinct from each other and as the Examiner stated in the previous Office Action (Requirement of Restriction) mailed December 5, 2006 "[t]he different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination" (see page 3).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 13, 2006.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-8 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for maize, does not reasonably provide enablement for any plant or even all monocotyledonous plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 1-8 are broadly drawn to a method of obtaining transformable callus tissue comprising germinating any mature seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce any growing seedling containing a nodal section; isolating said nodal section from said seedling; and culturing said nodal section to produce embryogenic callus suitable for transformation.

The specification fails to provide any guidance regarding the broad genus of mature seed and seedlings produced thereof that are used in the claimed method. The

specification only provides guidance for mature corn seed and seedlings produced thereof used in the claimed method (see, for example, page 33, paragraphs 0083 and 0085, page 37, paragraph 0098 and page 39, Table 3).

Claim 16 is broadly drawn to a method of obtaining transformable callus tissue from any plant comprising priming any mature seed, germinating said seed in tissue culture media containing any amount of any auxin and any amount of any cytokinin to produce any growing seedling containing a nodal section, isolating said nodal section from said seedling, and culturing said nodal section on callus induction media to produce embryogenic callus.

The specification fails to provide any guidance regarding the broad genus of mature seed and seedlings thereof and the broad genus of auxins and cytokinins used in the claimed method.

The specification only provides guidance for the use of corn seed and seedlings thereof (see, for example, page 33, paragraphs 0083 and 0085, page 37, paragraph 0098 and page 39, Table 3) and the use of the auxin picloram and the cytokinin BAP in the claimed method (see, for example, page 42, paragraph 0114, page 43, Table 4 and paragraph 0116, page 44, paragraph 0117 to page 45, paragraph 0118 and page 46, Tables 5-6).

Claim 17 is broadly drawn to a method of transforming monocotyledonous plants comprising priming any mature seed, germinating said seed in tissue culture media

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containing any auxin and any cytokinin to produce a growing seedling containing a nodal section, isolating said nodal section from said seedling, culturing said nodal section on callus induction media to form an embryogenic callus culture, transforming said culture with a nucleic acid sequence conferring a selected genetic trait to the transformed callus, selecting transformed callus cells, and regenerating a transformed plant from the transformed callus to obtain a plant containing the nucleic acid sequence.

The specification fails to provide any guidance regarding the broad genus of mature seed and seedlings thereof and the broad genus of auxins and cytokinins used in the claimed method.

The specification only provides guidance for the use of corn seed and seedlings thereof (see, for example, page 33, paragraphs 0083 and 0085, page 37, paragraph 0098 and page 39, Table 3) and the use of the auxin picloram and the cytokinin BAP in the claimed method (see, for example, page 42, paragraph 0114, page 43, Table 4 and paragraph 0116, page 44, paragraph 0117 to page 45, paragraph 0118 and page 46, Tables 5-6).

Zhao et al (Molecular Breeding 8:323-333, 2001) teach that various factors can affect the efficiency *Agrobacterium* mediated transformation in plants, such as the *Agrobacterium* strain used and the type of vectors that are used in the transformation (see page 323, 2nd column, 2nd paragraph to page 324, 1st column, 1st paragraph) and that plant genotypes have a large impact on transformation results (see page 330, 2nd column). Zhao et al also show factors such including antibiotics, plant culture media, *Agrobacterium* concentration, co-cultivation duration, and resting period need to be

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balanced against one another to achieve an overall high level of transformation (see page 330, 2nd column, 2nd paragraph).

Hansen et al (Trends in Plant Science 4(6): 226-231, 1999) teach that plant transformation is not an exact science, but more of an art because of the unique culture conditions required for each crop species and that to accommodate a species that has not been manipulated in culture previously one must either adapt an established protocol or create a new one, bearing in mind the efficiency imperatives (see page 230, 2nd column, 1st paragraph).

Given the claim breadth, the lack of guidance regarding the broad genus of mature seed and seedlings thereof and the broad genus of auxins and cytokinins used in the claimed method and the unpredictability of using *Agrobacterium* as taught in the art, it would have required undue trial and error experimentation for one skilled in the art to make and use the invention as claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Reichert et al (U.S. Patent 6,140,555, October 31, 2000). The claims read on a method of obtaining transformable callus tissue comprising germinating a mature seed

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in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section; isolating said nodal section from said seedling; and culturing said nodal section to produce embryogenic callus suitable for transformation (claims 1-8 and 16) or a method of transforming monocotyledonous plants comprising priming a mature seed, germinating said seed in tissue culture media containing an auxin and a cytokinin to produce a growing seedling containing a nodal section, isolating said nodal section from said seedling, culturing said nodal section on callus induction media to form an embryogenic callus culture, transforming said culture with a nucleic acid sequence conferring a selected genetic trait to the transformed callus, selecting transformed callus cells, and regenerating a transformed plant from the transformed callus to obtain a plant containing the nucleic acid sequence.

Reichert et al disclose a method of obtaining transformable callus tissue comprising germinating a mature seed in tissue culture media containing an effective amount of an auxin and an effective amount of a cytokinin to produce a growing seedling containing a nodal section; isolating said nodal section from said seedling; and culturing said nodal section to produce embryogenic callus suitable for transformation (claims 1-8 and 16) (see column 3, line 61 to column 5, line 67 and Tables 1-2; see column 10, line 65 to column 11, line 15) and a method of transforming monocotyledonous plants comprising priming a mature seed, germinating said seed in tissue culture media containing an auxin and a cytokinin to produce a growing seedling containing a nodal section, isolating said nodal section from said seedling, culturing said

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nodal section on callus induction media to form an embryogenic callus culture, transforming said culture with a nucleic acid sequence conferring a selected genetic trait to the transformed callus, selecting transformed callus cells, and regenerating a transformed plant from the transformed callus to obtain a plant containing the nucleic acid sequence (see column 3, line 61 to column 5, line 67 and Tables 1-2; see column 10, line 65 to column 11, line 15; see column 16, lines 25-43 and Table 8).

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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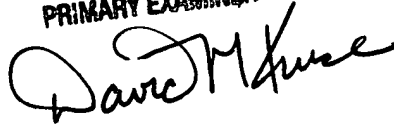
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

March 28, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over the printed name and title.